TITLE: **Research Involving Adults Who Lack Capacity to Provide Informed Consent**			DOCUMENT NUMBER: **IRB-005**
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IRB CHAIR OR DESIGNEE:	ACOS R&D:	COMPLIANCE:
Signature	Signature	Signature
Name	Name	Name
Date	Date	Date
5/11/04	May-13-04	5-14-04

1 POLICY

It is Stratton VA Medical Center's policy to comply with all applicable local, state, and federal regulations in the conduct of clinical research studies. Written procedures are required to guide the IRB in the review of research involving adults who lack the capacity to provide informed consent.

2 DEFINITIONS

Assent: An affirmative agreement to participate in research. Failure to object should not be construed as assent.

Human Subject: A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information, or individual who is or becomes a participant in research, either as a recipient of an FDA regulated test article or as a control. A subject may be a healthy individual or a patient.

Identifiable Private Information: Private information in which the identity of the subject is or may readily be ascertained by the investigator, or the identity of the subject is associated with the information.

Institutional Review Board (IRB): The Stratton VA Medical Center Institutional Review Board, formally designated by Stratton VA Medical Center to review, to approve the initiation of, and to conduct periodic review of biomedical research involving human subjects.

Legally authorized representative: An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. Legally authorized representative is synonymous with legally acceptable representative.

Minimal risk: Risk in which the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily

encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Private information: Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge or any experiment that involves an FDA regulated test article.

3 FORMS

None

4 REFERENCES

45 CFR 46
NYS Public Health Law
ICH Harmonised Tripartite Guideline For Good Clinical Practice (1 May 1996)

5 PROCEDURE

5.1 **Research not involving greater than minimal risk:** The IRB may approve research involving adults who lack capacity to provide informed consent and not involving greater than minimal risk, provided that the IRB finds and documents that:

5.1.1 The objectives of a trial cannot be met by means of a trial involving subjects who can give informed consent personally.

5.1.2 No greater than minimal risk.

5.1.3 Adequate provisions are made for soliciting the assent of the subject and the consent of the subject's legally authorized representative.

5.2 **Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects:** The IRB may approve research involving adults who lack capacity to provide informed consent and involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects, provided that the IRB finds and documents that:

5.2.1 The objectives of a trial cannot be met by means of a trial involving subjects who can give informed consent personally;

5.2.2 More than minimal risk is presented to the subjects;

5.2.3 The research holds out the prospect of direct benefit for the individual subject or is likely to contribute to the subject's well-being;

5.2.4 The risk is justified by the anticipated benefit to the subjects;

5.2.5 The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

5.2.6 Adequate provisions are made for soliciting the assent of the subject and the consent of the subject's legally authorized representative.

5.3 **Research involving greater than minimal risk and no prospect of direct benefit to the individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition:** The IRB may approve research involving adults who lack capacity to provide informed consent and that may involve more than minimal risk by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds and documents that:

5.3.1 The objectives of a trial cannot be met by means of a trial involving subjects who can give informed consent personally;

5.3.2 The risk represents a minor increase over minimal risk;

5.3.3 The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

5.3.4 The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition that is of vital importance for the understanding or amelioration of disorder, or condition; and

5.3.5 Adequate provisions are made for soliciting the assent of the subject and the consent of the subject's legally authorized representative.

5.4 **Waiver of assent:** The IRB may waive the requirement for assent of the subject when:

5.4.1 The capability of some or all of the subjects is so limited that they cannot reasonably be consulted;

5.4.1.1 In determining whether subjects are capable of assent, the IRB shall take into account the psychological state and physical state of the subjects involved.

5.4.1.2 This judgment may be made for all subjects to be involved in research under a particular protocol, or for each subject, as the IRB deems appropriate.

5.4.2 The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the subject and is available only in the context of the research; or

5.4.3 IRB determines that the assent may be waived according to the same criteria by which consent may be waived.

5.5 The IRB may waive some or all of the requirements for informed consent or may waive the requirement for documentation of informed consent (see Informed Consent SOP).

5.6 Consent of the legally authorized representative shall be documented in accordance with the Informed Consent SOP.

5.7 If subjects enrolled in the research develop the capacity to provide informed consent, the IRB may require consent of the subject in accordance with the Informed Consent SOP.

5.8 When the IRB determines that assent is required, assent shall be documented by having the subject sign and personally date the assent.